UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

THE HONORABLE ANDREW J. GUILFORD, JUDGE PRESIDING

CERTIFIED TRANSCRIPT

ALLERGAN USA, INC., et al., Plaintiff,

vs.

MEDICIS AESTHETICS, INC., et al., Defendants.

SACV-13-1436-AG

REPORTER'S TRANSCRIPT OF PROCEEDINGS

Santa Ana, California

August 12, 2014

SHARON A. SEFFENS, RPR
United States Courthouse
411 West 4th Street, Suite 1-1053
Santa Ana, CA 92701
(714) 543-0870

APPEARANCES OF COUNSEL:

For the Plaintiffs:

MICHAEL J. KANE
FISH & RICHARDSON P.C.
3200 RBC Plaza
60 South Sixth Street
Minneapolis, MN 55402
(612) 337-2502

LARA S. GARNER
FISH & RICHARDSON P.C.
12390 El Camino Real
San Diego, CA 92130
(858) 678-4332

ELIZABETH M. FLANAGAN
FISH & RICHARDSON P.C.
222 Delaware Avenue, 17th Floor
Wilmington, DE 19899
(302) 778-8472

For the Defendants:

DONALD G. NORRIS
NORRIS & GALANTER, LLP
523 W. Sixth Street, Suite 716
Los Angeles, CA 90014
(213) 232-0855

WILLIAM F. CAVANAUGH
SCOTT B. HOWARD
PATTERSON BELKNAP WEBB & TYLER, LLP
1133 Avenue of the Americas
New York, NY 10036-6710
(212) 336-2793

08:30

SANTA ANA, CALIFORNIA; TUESDAY, AUGUST 12, 2014; 9:04 A.M.

08:56 THE CLERK: SACV-13-1436-AG, Allergan USA, Inc., et al., versus Medicis Aesthetics, Inc., et al.

09:04 THE COURT: Good morning.

09:05 Let's have appearances, please.

09:05 MS. GARNER: Good morning, Your Honor. Laura Garner, and I have with me Michael Kane and Elizabeth Flanagan.

09:05 MR. NORRIS: Good morning, Your Honor. Donald Norris for the defendants.

09:05 MR. CAVANAUGH: Good morning, Your Honor. Bill Cavanaugh on behalf of the defendants.

09:05 MR. HOWARD: Good morning, Your Honor. Scott Howard on behalf of the defendants.

09:05 THE COURT: All right, welcome all. I hope you all received the tentative that was sent out.

09:05 I am prepared to describe how we should proceed, but I am also open to suggestions. Do the parties before me have any suggestions on how we should proceed?

09:06 MR. CAVANAUGH: Your Honor, we conferred briefly. Based on the Court's tentative ruling, it certainly appears that the Court understands the technology at issue in this case, and we don't think -- I don't think either side believes that a tutorial is really necessary.

09:06 THE COURT: I agree.

MR. CAVANAUGH: From our perspective at oral argument, there is only really one claim construction issue we would like to take up with the Court, and that's on the 2 to 20 percent degree of cross-linking issue.

THE COURT: I found that one of the most interesting. So you want to talk about 2 to 20 percent.

MR. CAVANAUGH: Right.

MR. KANE: Your Honor, as counsel said, we did discuss it the hallway, and we don't believe that a tentative is necessary.

THE COURT: You mean a tutorial.

MR. KANE: We don't believe that a tutorial is necessary. We have reviewed the tentative as well. We stand by our constructions and proposals that were submitted in the briefing, but in the sense of what we do today to accomplish and move things forward, Allergan is prepared to submit on the tentative and has no issues that it would like to raise with the Court. Obviously we would like a chance to respond to the defendants on the 2 to 20.

THE COURT: All right, let's hear 2 to 20. We will go back and forth on that. That really helps focus, and that's one of the reasons we issue tentatives.

MR. CAVANAUGH: Thank you, Your Honor.

THE COURT: By the way, it's always helpful to focus on any specific passages or lines or sections in the

tentative, but proceed as you wish.

MR. CAVANAUGH: Your Honor, I think it would be helpful if the Court has the '475 patent because I will refer to sections there. No graphics are really necessary.

THE COURT: Very well. I agree. I'll get the '475 patent. Go ahead.

MR. CAVANAUGH: Your Honor, in the tentative, you concluded that this was not a clear statement of the scope of the invention in column 9 at 30 to 34. The Court gave a number of reasons for that conclusion while noting I believe that it is a close question.

Let me start with column 9, Your Honor, and the language -- and the two sentences that follow that statement.

THE COURT: Just a moment. I have to gather the patent.

MR. CAVANAUGH: I know it's Exhibit A to Ms. Flanagan's deposition.

THE COURT: All right. I have it.

MR. CAVANAUGH: Column 9, Your Honor, line 30, this is what we are contending is the clear statement of the scope of the invention: "The degree of cross-linking in the HA component of the present compositions is at least about 2 percent and is up to about 20 percent." The two sentences that follow when read in context with that are simply

pointing out ranges that fall within 2 to 20.

Now, in its decision -- and, for example, it says: "In some embodiments, the degree of cross-linking is less than about 6 percent, for example, is less than about 5 percent. In other embodiments, the degree of cross-linking is greater than 5 percent, for example, is about 6 to 8 percent," and they talk about 4 to 12 percent.

Now, in its tentative, the Court noted, well, there's not necessarily a lower bound being provided, and the Court noted certain claims that refer to less than 6 percent and less than 5 percent. I have two points as to that, Your Honor.

The first is those are dependent claims. You have an independent claim that talks about the composition, which we would say is defined by 2 to 20 percent degree of cross-linking, so those are dependent claims.

The second point, and perhaps more importantly, is if you look at column 16 and you look at those dependent claims, claim 5 talks about less than about 6 percent. Claim 6 talks about less than about 5 percent, but then significantly, Your Honor, what the inventor does in dependent claim 7 -- it talks about the soft tissue filler of claim 4 wherein the HA composition has a degree of cross-linking of about 2 percent. He departs from using the phrase "less than" and specifically uses the phrase "of

about 2 percent" thereby following the language in the specification, which we say defines the scope of the invention, up to 20 and at least 2 percent.

THE COURT: If I were to say that range is not consistently applied throughout the specifications and claims, what would your response be?

MR. CAVANAUGH: I think it is applied consistently, Your Honor, because the only references to degree of cross-linking are always within 2 to 20 in all the examples that are provided. When they use the term "present composition," the inventor when talking about specific embodiments is very clear. He says, for example, in some embodiments -- in column 7 at lines 11, 20, 29, he uses the phrase "in other embodiments," column 7, line 18.

The Court notes that in one instance the inventor uses the phrase "present description," which is different from "present composition," but in that context, it's clearly a specific example -- and they're talking about column 14 -- that illustrates the release pattern of Lidocaine. So I think that there is a consistency throughout the specification. They're talking about this range, 2 to 20. That's what the inventor studied, and they define the clear scope of that invention.

Now, in its opinion, the Court notes, well, that's only used once. Two thoughts on that, Your Honor. The

first is if you look at the Astrazeneca case where they found that Astrazeneca based on a statement in the invention that the scope of the invention was simply the six identified salts, there is one reference to that in the specification. There is a vaguer description in the abstract, but if you focus on the body of the specification, in Astrazeneca, they just said it once.

If you think about it, this isn't the type of statement that you would necessarily repeat throughout the specification. You're saying here is my range. This is what I have invented, 2 to 20 percent, and then they go on to discuss the specific examples that follow.

The Court also notes an issue of claim differentiation, that claim 27 --

THE COURT: Well, isn't it superflous for claim 27 to be stating that if I were to adopt your definition, and isn't that a pretty powerful rule of construction?

MR. CAVANAUGH: I would say no, Your Honor, because if you look at the Astrazeneca case and the Edwards case, in both of those Federal Circuit decisions, the patentee raised claim differentiation. In Astrazeneca, there was a statement in the specification: The present invention is based on the following six salts. There is then a claim that recites those six salts.

Astrazeneca argued claim differentiation. Our

invention isn't limited to those six salts because there is a specific claim on it. The Federal Circuit disagreed and said, no, claim differentiation can't be used to override a clear statement of the scope of the invention.

THE COURT: Well, is this a clear statement of the scope of the invention?

MR. CAVANAUGH: It says the present composition and a range of 2 to 20 percent. I will give you a second example of where claim differentiation while a rule of thumb is not a rigid rule. In addition to the Astrazeneca case, the Edwards case, involving grafts that are intraluminally introduced into the body. The specification speaks of the term -- the claim spoke of the term "graft." The District Court claim construction said "graft" is defined as "intraluminal grafts." Even though the claim only says "graft," they added the term "intraluminal" based on the language of the specification.

Edwards argued we have a claim that says "inside of a vessel," and that's the definition of "intraluminal." Claim differentiation. Our claim should not be limited to intraluminal grafts because we have a claim that essentially says "intraluminal." Again, as in the Astrazeneca case, the Court disagreed and found claim differentiation could not be used in that instance to override a clear statement of the scope of the invention in the patent because the patentee

had referred throughout the specification to grafts as intraluminal.

So I don't think claim differentiation ends up being a powerful argument for the patentee in this instance, Your Honor, based on Astrazeneca and based on the Edwards decision. Here there is a clear unequivocal statement. Here is the range of the present compositions of my invention.

Finally, Your Honor, the Court noted that, well, this wasn't used to distinguish prior art, but that's not the sole test for whether there has been a clear statement of the scope of the invention.

THE COURT: Surely you don't think I am saying that's the sole test.

MR. CAVANAUGH: No, I didn't, Your Honor.

THE COURT: You mean it's a factor.

MR. CAVANAUGH: But the Federal Circuit -- for example, in the Edwards case, during the prosecution they deleted the term "intraluminal." Edwards said how could this be construed as limited to "intraluminal" when we deleted that term at one point during the prosecution history? The Federal Circuit said it wasn't material. Your deletion of it during prosecution wasn't particularly material, so you can't cite it.

Here, Your Honor, the fact that -- what didn't

come up during the prosecution history doesn't answer the question whether the inventor limited it for purposes of -- because if you look at all the prior art they cite, whether it was done for those purposes or whether because as the specification makes clear that's what they were testing. That was the range that they were testing.

So for all those reasons, Your Honor, we think this does come down to a clear statement. I think the language of those dependent claims strengthens that argument because if the inventor's view was I'm not bound by this 2 percent, why would that dependent claim be written differently than the two others? In that dependent claim, he confirmed not that 2 percent -- that's his lower boundary -- but that confirms what's in the specification.

THE COURT: Is it your position that the range 2 to 20 is consistently applied throughout the specifications and claims?

MR. CAVANAUGH: I believe it is, Your Honor.

THE COURT: Okay. Let's hear from the plaintiff, and that might be a good lead-off question to the plaintiff.

MR. KANE: Your Honor, we do not believe that it's used consistently throughout the specification or the claims. I think what is important is how often it is used, when it is used, and where it is used. I think you have to

look at the entire invention here.

I will refer the Court to the '475 Patent as well. I would start with the title of the patent, "Hyaluronic Acid-Based Gels Including Lidocaine." So that's the title. That's telling what the invention is about, adding lidocaine.

If you look at the abstract --

THE COURT: You know what I am going to ask you to do? Put it on the elmo.

MR. KANE: Your Honor, if you look at the abstract, the very first sentence says: "Disclosed herein are soft tissue fillers, for example, dermal and subdermal fillers based on hyaluronic acids and pharmaceutically acceptable salts thereof. In one aspect, the hyaluronic acid-based compositions include a therapeutically effective amount of at least one anesthetic agent, for example, lidocaine." There's nothing here about the degree of cross-linking. There is nothing here about that. It's all about the gel with the anesthetic agent.

We then continue through the patent. I'm referring to the Background Section, Your Honor. This is at column 2 starting at about line 29. They identify the problem that the patent is attempting to solve. "It has been proposed to incorporate certain therapeutic agents, for example, anesthetic agents such as Lidocaine." Then it

continues in the last paragraph of the background: "It is an objective of the HA-based soft filler compositions and methods of making them" --

THE COURT: "Making and using them."

MR. KANE: Yes. "Making and using them as described herein to provide soft tissue fillers that do not cause allergic reactions in patients, are biocompatible and stable and usable in vivo and include one or more local anesthetic agents." Again, there is no description about the degree of cross-linking or any kind of range of degree of cross-linking.

Then you move to the summary of the invention, the very first description of what the invention is. Again, Your Honor, the present description relates to soft tissue fillers, for example, dermal and subdermal fillers based on hyaluronic acid, and pharmaceutically acceptable salts of HA" -- and they give some examples -- "including a therapeutically effective amount of at least one anesthetic agent."

Then it continues. Again, Your Honor, in terms of is it consistent, this sentence is very important starting at line 42: "The present HA compositions describing the invention, including at least one anesthetic agent, have enhanced stability relative to conventional HA-based compositions, for example, Lidocaine," and it continues.

09:25 There is a description of the invention, the present HA compositions. There is no discussion about the degree of cross-linking.

The entire invention here, the disclosure, the problem that is being solved is this is going to tell the world how to make -- and it's the first of its kind of HA fillers -- that it can have Lidocaine that is stable and usable. That's the problem. It has nothing to do with the degree of cross-linking.

THE COURT: Hold on. I'm not getting that statement. Cross-linking does affect stability doesn't it?

MR. KANE: But the degree of cross-linking is not the novel invention. That's not the novel aspect of this. There were HA fillers that had a degree of cross-linking between 2 and 20 before this invention. There's nothing here where the applicant is saying other people have a degree of cross-linking at 50. Other people have a degree of cross-linking at 1. I have found out that the important range is 2 to 20. That's my invention.

It's not what this is about at all. It's all about being able to take an HA filler that has the desirable characteristics for the treatment and being able to add Lidocaine and maintain a useable stable product.

If you continue on in the summary --

THE COURT: Hold on just one moment.

MR. KANE: Certainly.

THE COURT: Why is there a mention of 2 to 20?

MR. KANE: Well, that is a range that was looked at, but that's not limiting, Your Honor.

THE COURT: When I asked a specific question about whether that range is consistently applied, you said no, correct?

MR. KANE: Correct.

THE COURT: But are all your inconsistent applications within that range?

MR. KANE: We don't think so, no. As I will show you, in the summary of the invention, there are inconsistencies. Again, at the very beginning of the patent --

THE COURT: Inconsistencies outside that range?

MR. CAVANAUGH: Yes. There are statements here, for instance, less than 5 percent at the very beginning of the patent.

THE COURT: Five percent is within the range of 2 to 20.

MR. KANE: One percent is less than five percent and is not within the range.

THE COURT: I understand your point.

MR. KANE: If you look at the summary of the invention -- we are at column 3, line 25. It says, "the

degree of cross-linking less than about 5 percent. Then it it continues, "for example, about 2 percent." It doesn't say greater than 2 percent. It doesn't say less than 5 and greater than 2. It says less than 5, for example, about 2.

THE COURT: Well, "about" is the phrase the defendants are proposing.

MR. KANE: I understand. I will come to that in a minute, but certainly it doesn't say greater than 2 or greater than about 2.

If we continue down to column -- again, we are still in column 3, lines 63 to 64. "The HA component has a degree of cross-linking of less than about 6 percent or less than about 5 percent." No mention of 2. It covers 1. It covers one-half. It covers three-quarters. Unequivocal.

Column 4 --

THE COURT: Unequivocal? You can't say that less than 5 percent unequivocally references 1 percent.

MR. KANE: I think it covers 1 percent. Unequivocally -- there is no limiting language about that.

THE COURT: Okay.

MR. KANE: Same thing in column 4. Again, still in the summary of the invention. "HA component having a degree of cross-linking of less than 5 percent."

THE COURT: When you're reading from it, I just want the record to be clear that it says, "less than about 5

09:30 percent."

MR. KANE: I apologize.

Then at line 17, it says: "HA composition with a degree of cross-linking less than about 5 percent." So in the Background Section, there is no discussion about the degree of cross-linking at all. It's all about adding Lidocaine. In the beginning of the summary of the invention, the discussion is about HA fillers with Lidocaine. There is no limitation at all on the amount of degree of cross-linking. Then here throughout the summary of the invention, there are four references to a degree of cross-linking, none of which have the 2 to 20 range, one of which says about 2, but three of which has no mention of 2 at all.

This is absolutely inconsistent with -- that the invention is limited and consistently limited to 2 to 20 percent. As the Court knows, the case law is very clear. The Phillips case is very clear. The Thorner case, which is a relatively recent Federal Circuit case, is again very clear. There are only two exceptions to this general rule that you get the plain meaning, lexicography -- they are not arguing lexicography here -- or a clear disavow of scope, meaning words of "manifest exclusion."

THE COURT: What are you reading from?

MR. KANE: I am reading from Thorner, "words of

manifest exclusion consistently and uniformly being used throughout the specification. They just aren't here, and the Court has noted that they're not here.

The other portions of the intrinsic evidence conflict with that interpretation. As the Court noted in its tentative order, this 2 to 20 percent doesn't ever appear except in claim 27, but it's never anywhere else in the specification. If that was important, if the invention was so limited, you would have expected to see this described elsewhere. You don't.

The Court also noted that -- again, claims 5, 6, and 7 that we just went through are also inconsistent. In fact, those claims come right out of the summary of the invention that I just went through. There is no discussion of 2 and 20 in the summary of the invention, so counsel's argument that claims 5, 6 and 7 confirm that we are in the range is actually completely inconsistent with the summary of the invention.

Actually I would argue claim 7 doesn't confirm any kind of a lower limit. If it was going to confirm some lower limit, there would be language such that it would say greater than about 2 percent, 2 percent or greater, something like that. This is actually calling out it's about 2 percent, which of course has to have some value below 2 percent. It's not saying 3 percent. That claim

wouldn't cover 6 percent. It only covers about 2 percent. So it's not calling out a range. It's calling out --

THE COURT: Patentable would be discovery of a 2 to 20 percent range -- the problem has been solved, and it's 2 to 20 percent. Do you think that would be patentable?

MR. KANE: I don't think so. I think the people who were doing this -- I think Allergan's previous products fell within that range. There's lots of products that fell within that range that are all prior art, so that can't be the novel aspect. That's not the invention here, finding a new range.

THE COURT: My question does not preclude it from being part of the novel aspect, but go ahead. I understand.

MR. KANE: That alone I don't think could be a distinguishing feature because there was present plenty of art out there that had cross-linking in that range.

As the Court noted, there is nothing in the prosecution history. These are the things that the cases have talked about being important.

If you look at the two cases that were cited in the briefs primarily -- one was the Honeywell case. In that case, the Court found that there was a limitation, but in that case, there were four separate statements that the Court relied upon, so it was uniform. It was consistent.

In the Astrazeneca case that counsel mentioned,

interestingly what the Court noted was that the very first sentence that described the invention had those six chemicals. Again, it was unequivocal. Here is our invention. Here are the six chemicals. It was in the very first sentence. So the Court found that that first sentence that told you what the invention was was unequivocal, and then the entire structure of the patent -- again, you have to look at the case. The facts are all specific in these cases obviously, but in that case, it was also the structure where they were claiming salts from certain categories. They didn't claim all the salts in the category. That's part of the Federal Circuit's analysis, too. They picked and chose.

So they went through and said we have a couple different categories of salts. We are going to take five from this one, not all of them. We are going to take one from this one, not all of them. Those are our six. That's our invention. Then later when the applicant tries to come back and says, no, no, no, we are not limited to those, but we can get other salts in those categories, the Court says, no, you can't. There is nothing like that here.

These cases are just completely different where you have got all these broad statements in the abstract. In Astrazeneca, the Court also noted the abstract was consistent. Comparing Astrazeneca to the '475 Patent, the

abstract doesn't mention anything about the degree of cross-linking. The first sentence in the first paragraph doesn't mention anything about the degree of cross-linking. Those are the portions of the patent that that Circuit focused on in Astrazeneca because right up front the applicants were telling the world here is our invention.

In this case, the applicants told the world what their invention was up front. Here is what the abstract say. Here's the problem we are trying to solve. Here is the summary of our invention. Never mentioned this 2 to 20 range. Later on in column 9 of the patent, there is a sentence. They are now trying to say that one sentence in isolation limits the entire disclosure. We think that's wrong. We think you got it right in the tentative, Your Honor.

The other point here besides the legal point is that in their briefing defendants set this up as an alternative argument. The Court may recall this is related to the water solubility or insolubility argument that the the Court has ruled upon and that the parties are now contesting.

So in their opening brief at pages 13 and 14, they said --

THE COURT: The Court has ruled upon -- you were contesting, and I ruled in favor of the defense on water

insolubility.

MR. KANE: We are not arguing that today. We are not arguing that in the tentative. You did rule against me on that point.

THE COURT: Against your client.

MR. KANE: Against our client. But in our opening brief at pages 13 and 14, again, they said it was an alternative argument, but if you don't include the water insolubility of the cross-link HA, then you have to include the 2 percent because we have to have some way to decide is the HA free HA or cross-linked HA? They repeated that in their reply brief at seven.

As you said, Your Honor, you ruled against Allergan on that point. The question I ask then is if they said it was in the alternative, why do they want it still? The reason is very simple. They are trying to manufacture a noninfringement argument, and it is completely inconsistent with the specification.

THE COURT: Do I take into account the purposes of claim construction?

MR. KANE: Well, I think it's instructive that before they had told you it's an alternative and now --

THE COURT: I should construe claims in the pristine world unaffected by what result it will have? It's kind of a little conversation I have had with my clerk over

here.

MR. KANE: I understand. I have dealt with judges in both camps.

THE COURT: And judges in this court.

MR. KANE: So let's just take a look at this. I think it's instructive because there isn't this interrelationship. They set it up as you need -- this limitation is necessary to distinguish free HA from cross-linked HA. Now, in that argument, they cited four prior art references that describe the cross-link HA as water insoluble.

As noted in the briefing, Allergan didn't ever contest that cross-linked HA was water insoluble. We just didn't think that was necessary in the construction. They have identified four references: The Calais reference, Exhibit 2; the Sadozai reference; Exhibit 4, the Debacher reference --

THE COURT: You have got the patent there, right?

MR. KANE: I do, Your Honor.

THE COURT: Are you citing references from the patent?

MR. KANE: No. I'm citing references used by the defendants to illustrate that cross-linked HA is water insoluble.

THE COURT: Understood.

MR. KANE: The final reference they cited is Lebreton, which is Exhibit 6. So they gave you four references, Your Honor, where they said here's where -- those skilled in the art say that water soluble -- cross-linked HA is insoluble. They have given you zero references where anyone makes a distinction between free HA and cross-linked HA based on the degree of cross-linking. It's always based on the degree of solubility, which the Court has ruled on.

Their stated purpose was that we need this limitation to distinguish between these two. The fact is you don't. For instance, we can show you the Tezel reference. This is at page 305 of Tezel that the Court cites in its tentative order. For instance, it says, "The total HA concentration consists of insoluble HA and soluble free HA."

So, again, the distinction between HA species -- there are two species in the total HA -- the total composition: The insoluble HA, the cross-linked HA; and the soluble-free HA. But it's not based on the degree of cross-linking.

Then continuing, at the bottom it talks about "The fluid component contains unmodified and modified soluble HA that is generated during the manufacturing process when the HA fragments are formed as a side product of the chemical

09:43 modification." And it continues at the very end of this
09:43 section: "It is important to understand how much of the
09:43 filler's concentration is gel or cross-linked HA and how
09:43 much is soluble fluid HA." So solubility or insolubility is
09:43 the distinction between free HA and cross-linked HA, and
09:43 it's not based on the degree of cross-linking. They haven't
09:43 shown you that. They can't show you that.
09:43 In fact, Your Honor, again to put this in
09:43 perspective, why are they still arguing this? Their product
09:43 has insoluble cross-linked HA particles with a degree of
09:44 cross-linking of less than 2 percent. If you were to impose
09:44 this limitation, there would be a summary judgment motion
09:44 they say they don't infringe.
09:44 The problem is this. They started off this whole
09:44 discussion with we have got this problem. We have got free
09:44 HA. We have got cross-linked HA. It has to fall into one
09:44 of those two camps, and we can't tell based on Allergan's
09:44 constructions. We could debate that, but there is no need
09:44 to. They have now created the opposite problem because they
09:44 have got undisputed -- this is based on public documents --
09:44 cross-linked HA particles less than 2 percent. So it's not
09:44 free HA because it's insoluble. Agreed upon definition.
09:45 It's not cross-linked HA. Why not? Because it's less than
09:45 2 percent. So now they have created this other undefined HA
09:45 category that's no longer free HA. It's no longer

cross-linked HA. It's something else.

So the entire premise of their argument that you have got to add the 2 percent in order to make this bright line between free HA and cross-linked HA falls apart. The bright line is the water solubility. This 2 percent is just an attempt to manufacture an infringement defense.

Again, with the description in the title, the abstract, the background of the invention, the summary of the invention, the claim language, the lack of discussion of this in the specification, the lack of -- it was mentioned one time -- the lack of it in the claims, there is just really no way that someone can come away with this and say this is really the invention. You have to limit the invention to 2 to 20.

So we think that it doesn't rise to the level of a clear disclaimer, which is what it has to have. There is no manifest words of exclusion here where they say our invention is limited to 2 to 20, and if you are outside that range, we don't cover it. Again, that's not what this was about. The invention was about adding Lidocaine and getting Lidocaine into these gels. That's what they taught. That's the novel aspect.

THE COURT: Thank you.

To close, sir, how much time do you need?

MR. CAVANAUGH: Three minutes.

THE COURT: I appreciate the argument of both counsel. It's very helpful.

MR. CAVANAUGH: Your Honor, we do think this is an aspect of a novel invention, not standing alone 2 to 20 percent, but what counsel never really squarely addressed is what's the purpose of that statement in column 9: "The degree of cross-linking in a HA component of the present compositions is at least 2 percent and is up to about 20 percent"?

What is that teaching a person of ordinary skill in the art when they read this? You look at the summary. They make it clear that cross-linking is an aspect of achieving a functional useful product. When you read this, you say, well, how do I achieve that? It's between 2 and 20 percent.

In column 3 that they point to --

THE COURT: Do you think the specification in that range would be patentable?

MR. CAVANAUGH: I don't know the answer to that standing alone. It might not be. I don't think that their Lidocaine addition is patentable because there was Lidocaine in the prior art. Frankly, from our position, we don't think any of this is patentable. Whether standing alone it would be, I don't know how precisely the claims would be phrased for it to try to be patentable, but it could

09:48 certainly be an aspect of a novel invention.

Because they are seeking to --

THE COURT: 2 to 20 might be the range that provides both stability and the ability to use with a smaller needle.

MR. CAVANAUGH: It's sufficiently viscous that it's a useable product. The purpose of this range of cross-linking is that we end up with something that is functional, that's usable. They are claiming that cross-linking is important to this process. In the summary, they talk about the cross-linking process, and then in column 3, they say less than 5 percent, about 2 percent.

I keep coming back to that dependent claim that says about 2 percent, and the two prior ones said less than 5, less than 6, and then they stop at about 2 percent.

THE COURT: Is 1 percent less than 5 percent?

MR. CAVANAUGH: 1 percent is less.

THE COURT: Does that act against your position?

MR. CAVANAUGH: Not when you read column 9. They describe the broad range, and then they give embodiments that are less than 5 percent, less than 6 percent. There is not a single example of 1 percent throughout the specification. In column 3 and in column 9 and in dependent claim 7, it's always 2 percent.

THE COURT: If I were to send you a settlement

letter and said my client is willing to pay you something less than $100,000, do you ever assume that can include $10, or would you assume I am willing to pay --

MR. CAVANAUGH: I wouldn't.

THE COURT: That's an argument in your favor.

MR. CAVANAUGH: It is.

THE COURT: Less than 5 percent -- if I said my offer is something less than $100,000, you would probably assume it's $99,000?

MR. CAVANAUGH: The point is context matters. My point is when you look at the specification -- the one sentence here is our range is 2 to 20. The next sentence says some embodiments are less than 5 percent. I wouldn't say, oh, you know what that means. That means I can use a .0001 percent cross-linking agent, and I am still within the scope of this invention. You wouldn't. That's why context matters. In the context here where they are talking about less than 5 percent, less than 6 percent, it comes after that sentence which describes the range.

THE COURT: To expand or maybe more focus the hypothetical, if I said will give you something less than five bucks for your hamburger, I don't think you would take a buck.

MR. CAVANAUGH: If I reached into my pocket and I had a quarter, I wouldn't think that that's the range you

were talking about.

THE COURT: Okay. So how much will you give me for a hamburger today? Why is the language there?

MR. KANE: Well, because again that is part of the range that they looked at. There is no doubt about that.

What counsel is missing, though -- let's look at column 9 because he is leaving out an intermediate sentence. The first sentence says about 2 to 20. He likes that sentence. The next sentence says between 4 and 12. So they put a lower limit there. They said 2 to 20, 4 to 12. You have seen patents, Your Honor. That's very common for patent owners that draft these things, 2 to 20, 4 to 12, preferably 6. That's very standard.

Here it says 2 to 20. The next line says 4 to 12. The next says less than 5. So where is the lower limit? They knew how to put a lower limit in. They did it right before. They said 4 to 12. If they wanted to say 2 to 5, they would have had said 2 to 5. They didn't. Context is important. That's the point I would make, Your Honor. When they wanted the claim ranges or to talk about ranges, they did, and they didn't do it on less than 5.

THE COURT: Okay.

MR. CAVANAUGH: Your Honor, as to the sentence counsel just quoted, he omitted the first three words that starts that sentence, "In some embodiments, the degree of

cross-linking is about 4 to 12," which follows the opening sentence, which is "the degree of cross-linking in HA component of the present compositions." Not some embodiments, some limitations. Start with the range. Then provide some embodiments.

Your Honor asked both of us the question where is the inconsistency? Did counsel come up and say, well, no, there is an example there where they are using 1 percent or 5 percent or 22 percent? None. None. That's why we say the specification is consistent, Your Honor.

THE COURT: Okay. Surrebuttal.

MR. KANE: Your Honor, again, it's not inconsistent as we said before. Again, if they wanted to say 2 to 5, they could have said 2 to 5. They didn't say it.

THE COURT: Okay. Counsel is the matter submitted?

MR. CAVANAUGH: Yes, Your Honor.

MR. KANE: Yes, Your Honor.

THE COURT: I will take it under submission. You can expect an order probably later today if I check out a few things I need to check out.

Where are we in the case?

MR. CAVANAUGH: We are in the process of document production.

THE COURT: Where are you in settlement discussions?

MR. CAVANAUGH: I know there have been some discussions between in-house attorneys, and I got an e-mail today that I think there will be some further discussions. That's really where we are.

THE COURT: Okay. On the way out, Counsel, just raise the issue of settlement and maybe talk about what the future would look like. I recently had a case come up for trial and was just about ready to call a jury, and they confessed they had not appeared before a third party in any of their settlement discussions. You are required to appear before a third party, and there are a few options available to you. I don't know if you have thought about that, a private company, a magistrate judge, or our panel of attorneys.

Have you decided amongst yourselves which of those would be preferred?

MS. FLANAGAN: I believe we selected private mediation in our scheduling order.

THE COURT: That's what I recall, too. So talk about how you might select someone as a private mediator. We have got some pretty good patent guys.

Anything else?

MR. CAVANAUGH: No, Your Honor.

09:56 THE COURT: Thanks for the argument. It was very helpful.

(Whereupon, the proceedings were concluded.)

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CERTIFICATE

I hereby certify that pursuant to Section 753, Title 28, United States Code, the foregoing is a true and correct transcript of the stenographically reported proceedings held in the above-entitled matter and that the transcript page format is in conformance with the regulations of the Judicial Conference of the United States.

Date: August 14, 2014

/s/ Sharon A. Seffens 8/14/14

SHARON A. SEFFENS, U.S. COURT REPORTER